



## U.S. REGULATION of BIOLOGICS and BIOPHARMACEUTICALS

- FDA Policies and Expectations •

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To be announced

Time to market is crucial for the economic success of any new product. Yet, before a new therapeutic may be marketed, companies have to meet a significant number of regulatory requirements that prove to regulatory authorities that the new therapeutic is safe and efficacious and that it can be produced to predetermined specifications by a reliable manufacturing process.

This course clarifies the unique policies and expectations of FDA's Centers for Biologics Evaluation and Research (CBER) and Drug Evaluation and Research (CDER) with the goal of helping companies anticipate, and thus avoid, regulatory problems which have the potential to delay product approval. Specific CBER/ CDER manufacturing concerns, the locations of potential "red flags" in applications, common shortcomings in clinical trial design, and regulatory issues which can result in an IND being placed on clinical "hold" will be addressed.

At the end of this course you will know how to most effectively communicate with FDA and what information the Centers expect in an IND and the NDA/BLA. You will also have a solid understanding what to expect during regulatory inspections.

### Course Content:

#### Overview of the Regulation of Biologically derived Products and the IND Process

- What is a Biologic? What constitutes a Biopharmaceutical?
- Pertinent Laws and Regulations
- Product Jurisdiction and Organization of CBER and CDER
- What to expect from the transfer of biopharmaceutical product regulation from CBER to CDER
- The Investigational New Drug Application (IND) Process
  - "Nuts and Bolts" of the IND Application The Forms 1571 and 1572 - The CMC Section Preclinical Studies - Phase I Clinical Trial Issues
- Types of IND's including Treatment and Emergency IND's
- Product and Clinical Development under IND
- The Pre-IND Process
- Meetings and Communications with the FDA during the IND Process
- ICH Guidelines

### IND Case Study The License Application and The Food and Drug Administration Modernization Act (FDAMA) of 1997

- The License Application (LA)
  - The LA for Biopharmaceutical Products
  - Implementation of the LA for all Biologic Products
  - The Managed Review Process
  - The Refuse-to-File Policy
  - FDA Advisory Committees
- The Impact of the FDAMA of 1997
  - "Fast Track" Designation
  - FDA Meeting Policy
  - Effects of FDAMA on License Application Review
  - License Application Case Study

### Manufacturing and Establishment Issues

- Manufacturing and Product Characterization Issues
  - The Pilot Manufacturing Facility Policy
  - 21 CFR 601.12 - Changes to be Reported (1997 revisions)
  - Product Characterization and Lot Release Issues
  - Manufacturing "Scale-Up" Issues
  - Comparability Protocols and Product Manufacture Bridging
  - Technology Transfer Issues
- Establishment and Inspection Issues
  - Process Validation Issues
  - Quality Assurance and Quality Control Overview
  - "TEAM BIOLOGICS" and Inspection of Manufacturing Facilities
  - Contract Manufacturing
- Product Manufacture and Bridging Case Study

### Upcoming Regulatory Issues

### Course Faculty:

**Jeanne M. Novak, Ph.D.** served as the BLA Project Manager at FDA's Center for Biologics Evaluation and Research (CBER). In this position, Jeanne coordinated efforts for future implementation of a single Biologics License Application (BLA) for all CBER-regulated products. She also served as the primary reviewer of over seventy IND's and as the regulatory coordinator for over twenty PLA's and numerous labeling submissions. Jeanne has coordinated sessions for advisory committee meetings and has conducted numerous pre-license inspections while at FDA.

She received her Ph.D. in Experimental Pathology and a B.S. in Biology from the University of Utah. Prior to joining FDA, she conducted scientific research at the United States Army Medical Research Institute of Infectious Diseases at Fort Detrick, MD. Jeanne is an active member of ASM, DIA, RAPS, IABS, FDLI and PDA and a frequent speaker at regulatory conferences and seminars.

Currently, Jeanne is the Principal Consultant of CBR International where she provides expert regulatory advice on requirements for biological, pharmaceutical and device product development.

### You will benefit from this course, if you belong to the

regulatory affairs department, process development personnel, R&D staff, validation personnel, QA or QC staff or manufacturing department of a CBER-regulated company.

Employees of Clinical Research Organizations and anybody who needs a more thorough understanding of the U.S. regulatory process of biologics and biopharmaceuticals will also greatly profit from this course.

This course is also available as an **in-house course** at your facilities!

### Venue:

To be announced

When making your hotel reservation, please mention the **Center for Continuous Education** to receive the **special group rate!**

### Course Schedule:

Each Course Day:  
8:00 a.m. to 4:00 p.m.

### Fee Schedule:

\$1,695 for early payment  
\$1,795 for payment received by closing date  
\$1,895 for payment received after closing date

To assure your participation,  
**REGISTER EARLY!**

### For Registration...

we only need your **name, affiliation, postal address, and phone and fax numbers** together with the **course title**. You can **call, fax or e-mail** us the information or you can register through our **web site**.



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### The Unavoidable Small Print!

The course fee includes a **comprehensive course book** containing the complete presentation material. It also covers **continental breakfast** and **refreshments** served in the course room and **lunch** on course days. Course participants will receive a **certificate** confirming 1.8 CEU's.

Course acceptance is based on a **first come, first served basis**. To hold your place as a confirmed participant, CCE must receive your **payment made with check or major credit card by the course closing date**. CCE must have received your payment at the latest 5 business days prior to course start.

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